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PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	David McMorrow, Henrick Hansen and Tom McHale
Application No.:	10/087303
Filed:	February 28, 2002
For:	BALLOON FOLDING APPARATUS, METHODS AND PRODUCTS
Examiner:	Charles H. Sam
Group Art Unit:	3731
Firm Docket No.:	S63.2B-9719-US01

DATE: November 7, 2005 TIME: 3:53 P.M. FACSIMILE NO.: 571-273-8300

TOTAL NUMBER OF PAGES (including transmittal letter): 10

## FACSIMILE TRANSMITTAL LETTER

In addition to this 2 page Facsimile Transmittal Letter, following please find a 1 page Notice of Appeal in duplicate (2 pages); 1 page Pre-Appeal Brief Request for Review; 1 page Petition for Extension of Time; and 4 pages Reasons For Pre-Appeal Request For Review.

With respect to fees: ☒ Please charge the \$500.00 filing fee and the one month extension fee of \$120.00 to our Deposit Account No. 22-0350

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If any extension of time for the accompanying response is required or if a petition for any other matter is required, applicant requests that this be considered a petition therefore.

If any additional fees associated with this communication are required and have not otherwise been paid, please charge the additional fees to Deposit Account No. 22-0350. Please credit overpayment associated with this communication to the Deposit Account No. 22-0350.

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By

William E. Anderson II  
Registration No.: 37766

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**Transmittal Letter**  
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**Application No.: 10/087303**

**Attorney Docket No.: S63.2-9719-US01**

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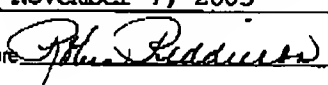

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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		<b>Docket Number (Optional)</b> S63.2-9719-US01	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>November 7, 2005</u> Signature <u></u> Typed or printed name <u>Robin Peddieson</u>		<b>Application Number</b> <u>10/087303</u>	<b>Filed</b> <u>February 28, 2002</u>
		<b>First Named Inventor</b> <u>David McMorrow, et al.</u>	
		<b>Art Unit</b> <u>3761</u>	<b>Examiner</b> <u>Charles H. Sam</u>
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.  This request is being filed with a notice of appeal.  The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the <input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) <input checked="" type="checkbox"/> attorney or agent of record. <u>37766</u> Registration number _____ <input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____		 Signature <u>William E. Anderson</u> Typed or printed name <u>952-563-3008</u> Telephone number <u>November 7, 2005</u> Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
<input checked="" type="checkbox"/> Total of <u>3</u> forms are submitted.			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**REASONS FOR PRE-APPEAL REQUEST FOR REVIEW**

Applicant hereby requests that the Advisory Action issued in this case on October 19, 2005, be overruled and that the case be remanded to the Examiner because the rejections, which are discussed below, are clearly in error and not justified.

With regard to the rejection of claims 21-24, 26, 29 and 30 under 35 USC §102(e), it is asserted in the Office Action that they are anticipated by Whalen et al. (2002/0107540). The rejection is in clear error because, among other reasons, it is based on a clear mischaracterization of the structures disclosed in Whalen et al. In support of the rejection, it is asserted by the Examiner that "the splines 260 can be inflated or deflated by inflation or deflation of fluid." (See page 4 in the Response to Arguments section of the Final Official Action. The statement was made in reference to Applicant's arguments and in reference to figures 4-4a and the corresponding disclosure of Whalen et al.) The rejection is in error because there is absolutely no support for this statement. Not only is there no support for asserting that the splines 260 of Whalen et al. can be inflated or deflated, there is no indication that the anchor body 264 on which the splines 260 are mounted can be inflated or deflated.

In addressing the splines, it is stated in paragraph 0049 of the reference that

"FIG. 4/4A illustrate bladder engaging elements comprising spaced-apart, preferably padded, splines 260. The padded splines 260 radially extend from the exterior surface of, or are otherwise integral with, the surface of the anchor body 264, in this particular configuration, a proximal end portion 54 of the elongate member. The padded splines 260 include, or more particularly radially terminate in, a urinary tract engaging head 261 which provides an increased area for contact with the structures of same, thereby providing a more gentle engagement therewith. As the case with the configuration of FIGS. 3/3A, urine "flow through" may be advantageously achieved."

The description states that the splines are spaced apart and engage the bladder. They are described as padded and extend from the anchor body 264 in the particular configuration

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shown. The splines 260 have an engaging head 261 to engage the walls of the bladder. The configuration, as shown in figure 4 and 4A, is also stated to allow urine to flow through between the splines. Nowhere does it state that the splines 260 can be inflated or deflated by inflation or deflation of fluid, as asserted in the office action in support of the rejection. There is nothing in the reference that indicates that the splines are anything other than solid pieces radially extending from the anchor body 264 which are shaped to come in contact with the wall of the bladder while at the same time allowing the flow of fluid. The only other discussions of the construction and purpose of the splines, which are found in paragraphs 0051 and 0052, also fail to describe the splines as any thing other than radially extending solid pieces that engage the walls of the bladder. They certainly are not described as being balloon-like and being capable of being inflated or deflated by inflation or deflation of fluid, as asserted in the official action. As such, for the reasons stated above, the rejection is based on a clear mischaracterization of the disclosed structure of the cited art and the rejection therefore should be overturned and the case should be remanded to the Examiner.

With regard to the rejection of claims 25, 39 and 40 under 35 USC §103(a) as being unpatentable over Whalen et al. in view of Butaric et al. (US 6033380), among other reasons, since the rejection depends upon the rejection of claims 21-24, 26, 29 and 30, it similarly should be overturned for the reasons stated above.

The rejection of claims 21 and 29, which were rejected under 35 U.S.C. 103(a) as being unpatentable over Gaudoin et al. (6,296,655) in view of Hillstead (5,116,318), should also be overturned for clear error.

The rejection is clearly in error because, not only does Hillstead fail to provide the asserted disclosure, there is absolutely no motivation to make the combination asserted in the rejection. Only in clear hindsight of Applicant's disclosure might such a combination be made. The figures pointed out in the rejection, figures 4 and

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8, show a cross-section of the devices shown in 3 and 7, respectively. The balloon 34 is shown in its partially deflated shape in figure 2. As can be seen, no predetermined folding condition is shown or discussed. The elastic sleeve 40 around the balloon has a small resting diameter, such that, when it is at rest around the balloon 34, it constricts the balloon 34. There is no teaching regarding the folding of the balloon prior to constriction. The cross-sectional view of figure 4 is merely a random portion of the balloon. There is no mentioned significance of the configuration shown. The same is true for the configuration of the balloon shown in figure 8, which illustrates the balloon *subsequent* to expansion and deflation. The elastic sleeve forces the balloon down when pressure is relieved. The configuration of the balloon is given absolutely no significance other than that the flattened "wing-like" portions 21, 22, which are typically formed *after* deflation of the balloon, as shown in figure 1, are held down by the elastic sleeve, as shown in figure 8, for safe withdrawal of the catheter.

Gaudoin et al., on the other hand, deals specifically with folding techniques and configurations. One skill in the art would have no motivation to alter teachings dealing specifically with predilatation balloon folding configurations, as illustrated in Gaudoin et al., based on the disclosure of Hillstead, which offers no predilatation balloon folding teachings. The random cross-sectional configuration pointed out in the official action shows nothing more than the relative positions of the stent 32, the elastic sleeve 40 and the balloon 34 and that the elastic sleeve forcibly constricts the balloon. As a consequence, there is clearly no reasonable motivation which could be constructed from the references to support the combination asserted by the Examiner. The Examiner's obvious rejection is clearly not justified.

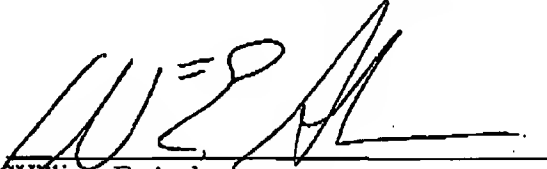
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For the above reasons, the outstanding rejections were made in clear error and it is hereby requested that the they be overturned and that the application be remanded to the Examiner for continued prosecution.

Respectfully Submitted,  
VIDAS, ARRETT & STEINKRAUS, P.A.

Date: November 7, 2005

  
William E. Anderson  
Attorney Reg. No.: 37766